DETAILED ACTION

1. This office action is in response to applicant's amendments filed on July 6, 2009.

2. Claims 1-27 are pending. Claims 1 and 11 have been amended.

3. The objection to the Oath and abstract are withdrawn.

4. The objection to claim 11 is withdrawn in view of applicant's amendments to the claim.

5. The rejection of claims 1-27 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's amendments to claim 1.

6. Claims 1-16,19-23 and 25-27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lykke et al. (US 6,242,405) for the reasons set forth in the previous office action.

7. Claims 17,18 and 24 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lykke et al. (US 6,242,405) in view of Gutierrez et al. (US 5,739,093) for the reasons set forth in the previous office action.

Response to Arguments

8. Applicant's arguments filed regarding Lykke et al. have been fully considered but they are not persuasive. The applicant argues that the instant application exhibits unexpected superiority when compared with the composition of Lykke. The examiner respectfully disagrees and argues that the showing of Lykke is for Lipolase while Tables I and II are directed towards proteases and amylases. This is not a direct comparison since the enzymes are different. Lykke further teaches enzymes such as proteases and amylases but has not provided stability data for them. Applicant has not performed experiments comparing the compositions of Lykke to the instant invention. Furthermore, the results Lykke show in the examples are not limiting of the invention. Also applicant's showing is not commensurate in scope with the instant claims which are not limited to the species proteases and amylases, the percentages of water and salt and the particular salts of the examples. A reference is not limited to the working examples, see *In re Fracalossi*, 215 USPQ 569 (CCPA 1982).

Optimization of the amount of salt in the non-aqueous portion of the composition would affect diffusion parameters and would ultimately affect release of the enzyme prematurely, and storage stability is a recognized parameter in the Lykke reference. Optimization of variable which effect storage stability would only require routine skill in the art and the skilled artisan would have been motivated to arrive at "at least 70%" of the non-aqueous component of the compositions comprising water-soluble ionic salt.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMINA KHAN whose telephone number is (571)272-5573. The examiner can normally be reached on Monday through Friday, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on (571) 272-1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lorna M Douyon/
Primary Examiner, Art Unit 1796

/Amina Khan/
October 15, 2009